SECRETARÍA DE
AGRICULTURA, GANADERÍA,
DESARROLLO RURAL, PESCA Y ALIMENTACIÓN

Consejería Agroalimentaria para EUA

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Washington, D.C. April 4th, 2003

Joseph Levitt
Director, Center For Food Safety and Applied Nutrition
Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Comments of the Secretaria de Agricultura, Ganaderia, Desarrollo Rural, Pesca Y Alimentacion ("SAGARPA") On the Notice of Proposed Rule to Implement Provisions of the Bioterrorism Act of 2002 - -- Registration of Food Facilities (Section 305) - - **Docket No. 02N-0276**

On behalf of the Secretaria de Agricultura, Ganaderia, Desarrollo Rural, Pesca y Alimentacion ("SAGARPA"), the Agriculture Department of the Government of Mexico, we are submitting these comments on the above captioned proposed rule addressing registration of food facilities promulgated pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act of 2002"). 68 Fed. Reg. 5377 (2003).
As a threshold issue and as a good neighbor sharing a 2,000 mile border, SAGARPA understands the desire of the United State --or indeed any country-- to ensure the safety of its citizens and the security of its food supply. We would be pleased to work with you to reach this goal in a reasonable and realistic manner so as not to unnecessarily disrupt trade and economic integration.

For the calendar year 2002, total exports of food from Mexico to the United States were were $6.3 billion dollars. Mexican exports of fresh produce to the United States were roughly 7 billion pounds valued at more than $2.4 billion. Mexico is proud of the increase in trade and economic integration between the United States and Mexico, especially since the implementation of the North American Free Trade Agreement.

We would like to bring to your attention that the demand for fresh produce by U.S. consumers is increasing as the health benefits of fresh produce become well-known. Mexico supplies many varieties of produce that are not grown in the United States during many months of the year. Our request is that you keep this trade and U.S. consumers demand for these Mexican products in mind as you implement this regulation.

The proposed rule issued on February 3, 2003 by FDA would govern food facility registration pursuant to Section 305 of the Bioterrorism Act of 2002. The regulation would require Mexican facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003.

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SAGARPA understands that the goal of the new registration requirement is to assist FDA in responding to a threatened or actual terrorist attack on the U.S. food supply. For FDA, registration would provide timely information to FDA about all facilities that manufacture, process, pack, or hold food for consumption in the United States. In the event of an outbreak of food-borne illness, such information will help FDA and other authorities to determine the source and cause of the event, and to notify promptly the facilities that might be affected by the outbreak.

I. Potential Burdens to Trade

SAGARPA's primary concern with respect to this provision is that it not be overly burdensome for foreign facilities, and that it not be used as an impediment to the importation of food products into the United States.
SAGARPA notes that FDA proposes to require information beyond that mandated by the statute. Because of the scope of the proposal, the amount of information required or requested, and the need for timely information updates, SAGARPA sees a potential for the FDA registration database system to become clogged, with adverse consequences for trade between the U.S. and Mexico. We would urge FDA to keep the registration form as simple as possible without hampering its ability to identify sources of food contamination.

We understand that under the regulations foreign facilities can designate a U.S. agent for registration, and that FDA encourages, but does not require, a formal agreement or "authorization" between parties. As a practical matter, virtually all exporters will have to employ a U.S. agent in order to export to the United States. For small Mexican producers and exporters (which are numerous because the industry is less concentrated than others) this requirement will be a significant additional cost of doing business, and may in some instances force them to cease sending product to the U.S. market.

With regard to the burden that will be imposed, FDA appears to have underestimated the complexity of the registration, the number of facilities that would be required to register, and the annual reporting burden on facilities and parent firms. FDA particularly appears to have underestimated the number of transportation/shipping facilities, which would be required to register since they hold food in transit.

Another significant cost and uncertainty for international trade results when an import is placed on hold because the facility is not registered with FDA. The owner, purchaser, importer, or consignee is responsible for placing and paying for secure storage, even though none of them may have had responsibility or involvement in registration.

II. WTO and NAFTA[1] Inconsistencies

A. Technical Barriers to Trade Issues

[1] The discussion is in terms of the WTO but in most instances there is a parallel or identical NAFTA provision.

On February 13th, 2003 the Secretariat of the Committee on Technical Barriers to Trade (CTBT) of the World Trade Organization (WTO), delivered the notification G/TBT/N/USA/32 in which United States presented the Bioterrorisem Act. On February 6th, 2003 the Committee on Sanitary and Phytosanitary Measures of the WTO under notification G/SPS/N/USA/690, was notified about the Bioterrorism Act. However, the Bioterrorism Act was not notified under the Technical Barriers to Trade ("TBT") Agreement, which Mexico maintains is inconsistent with WTO/TBT requirements.

With regard to the TBT, Mexico makes the following points and requests:

- Mexico requests that the United States, according to articles 2.5 and 2.9.3 of the TBT, explain in detail its justification of the registratione measure. According to the 2.9.4 of the TBT Agreement, Mexico requests that the United States maintain communication on the development of the final regulation.

- Assuming that the regulations does go into effect, Mexico requests that the United States provide technical assistance to assist Mexican exporters to accomplish the necessary corresponding legal norms and compliance methods, considering the complexity, including new concepts, requirements, prerequisites, prescriptions and features being established.
- Pursuant to article 12.3 of the TBT, Mexico requests that the United States explain the steps being taken to ensure that this new measure will not create an unnecessary obstacle to trade.
- According to Article 2.9 of the TBT Agreement, Members are required to: i) announce to the members through a notice , in an early stage, its intention to adopt the regulation ii) notify, also in an early stage, the objective, reason and products affected by the regulation, to allow the Members to formulate comments iii) provide details about the contents of the technical regulation project and indicate their differences regarding applicable international standards and norms iv) provide a schedule, in a reasonable timeframe, for the formulation of observations, to maintain dialogue and consider such observations and conversations. The United States failed to meet these transparency requirements.
- Under the TBT, Article 2.2, technical regulations should have a legitimate objective if they are mandatory. Otherwise, the measure is an unnecessary obstacle to international trade.

D. Sanitary and Phytosanitary Agreement

The registration regulation also is inconsistent with the Sanitary and Phytosanitary Agreement of the WTO ("SPS"). Under Article 2.1 and 2.2 of the SPS, any measure taken to protect human or plant health must have a scientific basis. Mexico does not believe that the Bioterrorism Act and the registration regulations have a scientific basis in the sense contemplated by the SPS. The Act and regulations were put forward very quickly in response to a national terrorism attack and no scientific analysis of the likelihood of risk to human or plant health was conducted.

E. Agreement on Import Licensing Procedures

The registration regulation is an import license in that it is an administrative procedure requiring the submission of an application or other documentation (other than that required for customs purposes) to the relevant administrative body as a prior condition of importation. The effective requirement of the registration regulation is that a U.S. agent will have to attest on behalf of the Mexican facility and an agent will have to be maintained in the United States for this purpose. This new requirement is costly for the Mexican agriculture sector, a sector made up of many farmers across Mexico. This effective requirement is not consistent with Article 1.2 of the Licensing Agreement which requires that administrative procedures to implement licensing requirements must be with a view to prevent trade distortions and take into account the economic development and financial and trade needs of Members.

VIII. Mexico Proposes the Following Alternatives

Assuming that the United States, in spite of the commentaries made, imposes these measures, the Government of Mexico proposes the following: (which does not imply in any way recognition from Mexico about the validity of the possible measures adopted by the United States --and consequently Mexico reserves without prejudice the ability to exercise its rights within the framework of the WTO and the NAFTA):

- ***Guarantee of confidentiality***: Mexico asks the United States to guarantee that the information the companies present will be kept strictly confidential, and that information will be handled in a way so as to avoid any risks.

- ***Guarantee electronic system***: Guarantees of functionality of the electronic system must be made in order to avoid delays and involuntary omissions to the regulation

III. Chart of Specific Issues

Location	*It states*	*must state/Comments*
IIIC2, pp 5384	Given FDA´s preference for electronic registration and the ease of electronic registration for both registrants and FDA...	In Mexico, according to the Federal Register estimation (pp 5395), only 3,38% of the population have access to the Internet which would make Mexican companies extremely difficult to register electronically
Part 1H1.231 pp 5418	...You will be considered registered once FDA electronically transmits your confirmation and registration number unless notified otherwise	The FDA must be clear, in relation to what another form of notification can be made. If it is different from the electronic one and if it recommends it, this can also be applied to the prior notice of shipments. It is convenient to clarify how long the notification can be expected.

Location	It states	must state/Comments
Part 1H1.241 pp 5419	(a)Failure of a domestic or foreign facility to register in accordance with this regulation is a prohibited act under section 301 of the act (21 U.S.C. 331)...	Mexico requests to the FDA the establishment of a consultation area to take care of diverse doubts as well as, to verify that it is registered, in order to fulfill the rule and to avoid a legal action of the American authorities against an exporter. It is also necessary to specify the sanctions and the criteria to assign them according to the amendment of the FFDCA which considers a federal crime not to have a registration.

In summary we believe that the registration regulation could be burdensome to trade without providing addition security to the U.S. food supply. Furthermore, the regulation may violate the WTO and NAFTA. We hope that FDA will take these points into account in drafting its final regulations.

Sincerely,

Enrique Lebo
Minister
Agricultural Office
Embassy of Mexico